

FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE SFBC INTERNATIONAL, INC.
SECURITIES & DERIVATIVE
LITIGATION

MDL No. 1777 (SRC)

Civil Action No. 06-165 (SRC)

THIS DOCUMENT RELATES TO: THE
CONSOLIDATED DERIVATIVE ACTION

AMENDED OPINION

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CHESLER, District Judge

This matter comes before the Court upon the motion filed by Defendants Jack Levine, Gregory B. Holmes, David Natan, Marc LeBel, E. Cooper Shamblen, David Lucking, Arnold Golieb, Lewis Elias and Leonard I. Weinstein to dismiss the Verified Consolidated Derivated Complaint (“Complaint”) pursuant to Federal Rules of Civil Procedure 12(b)(6) and 23.1 [docket item # 94]. Defendant SFBC International, Inc., now known as PharmaNet Development Group, Inc., joins in the individual Defendants’ motion to dismiss [docket item # 98]. (Hereinafter, the individual Defendants and PharmaNet Development Group, Inc. will be referred to collectively as “Defendants.”) The Court has considered the parties’ submissions in support of and in opposition to this motion, and, pursuant to Federal Rule of Civil Procedure 78, rules on the

motion based on the papers submitted. For the reasons that follow, the Court denies Defendants' motion to dismiss.

I. BACKGROUND

This shareholder derivative suit arises from the alleged mismanagement of SFBC International, Inc., now known as PharmaNet Development Group, Inc. ("PDG"), a company engaged in the business of providing clinical testing, development and consulting services to pharmaceutical and medical device companies. (For simplicity, this Opinion will refer to the subject company as "PDG".) The breach of fiduciary duty and mismanagement claims asserted in this lawsuit concern a broad range of alleged misconduct, from improper personnel choices to the failure to rectify unethical clinical testing practices and unsafe conditions at the company's flagship Miami testing facility. The following synopsis of the facts is drawn from the allegations of the Complaint, and the Court assumes their truth for the purpose of this motion only.

According to the Complaint, PDG provides a range of early and late stage clinical drug development services to branded pharmaceutical, biotechnology, generic drug and medical device companies worldwide. During the period at issue in this lawsuit, that is, August 2003 to January 2006, PDG operated clinical trial facilities in Miami and Fort Myers in Florida and Quebec City and Montreal in Canada. The company was headquartered in Miami, with corporate offices located in the same building as the Miami testing facility.

During the relevant period, PDG engaged in a strategy of growth and expansion, motivating it to secure lucrative contracts by assuring pharmaceutical companies that it could quickly enlist study participants and process clinical trials at its large Miami facility. Plaintiffs charge that to deliver these promised services, PDG violated proper and ethical clinical practices

and procedures, putting the safety of the human participants in the studies at risk and providing the client companies with inaccurate or falsified reports about the products being tested. Many test participants were uneducated, low-income U.S. citizens or immigrants, who were baited with payment plans that were designed to assure that they would not drop out of a trial or report adverse reactions. For example, the Complaint states that participants were paid only \$66 per day for the first nine days of testing, but offered payment increases of 500% per day for the last three days of a test. PDG employees provided these participants with inadequate disclosures about the dangers of the trials in which they were enrolling. Immigrant participants were threatened with deportation if they did not cooperate with the company's scheme to underreport negative experiences during the trials. Further detailing how the participants' health was put at risk, the Complaint recounts an example of a Haitian immigrant with active tuberculosis being permitted to participate in a study at the Montreal facility. Numerous other people housed at the Montreal facility tested positive for latent tuberculosis, including the Haitian immigrant's roommate at the facility, a Kuwaiti immigrant whose demands to be moved to another room were ignored for days.

In addition to inducing participants to falsify or suppress information, those running the PDG clinical trials also contaminated test results by allowing participants to overlap tests. Participants were permitted to participate in back-to-back tests, without abiding by the minimum waiting requirements set by the Food and Drug Administration ("FDA"). No effort was made to determine whether participants were simultaneously involved in other trials conducted by other clinics. The Complaint charges that PDG's directors took no action to remedy these egregious violations.

The Complaint further charges that, to conceal these unethical and/or illegal practices, PDG worked with two Institutional Review Boards (“IRBs”)¹ which had conflicts of interest preventing them from conducting unbiased reviews of the clinical trials. One of them, Southern IRB, was owned by the wife of defendant Cooper Shamblen, vice president of clinical operations. PDG also used an IRB called Lee Coast, which Plaintiffs allege shared offices with PDG’s Fort Myers’s subsidiary. Plaintiffs allege that Lee Coast employees were paid directly by PDG’s accounting office and that Lee Coast did not maintain its own books and records.

The FDA detected problems with PDG’s clinical practices. PDG received at least seven Form 483 citations from the FDA during the relevant period.² The FDA conducted inspections of the testing facilities and identified various improper practices, including that PDG employees were giving test subjects additional medication, such as Ibuprofen and skin cream, without informing the drug manufacturer that sponsored the tests; that the company changed test results to please a client; and that persons with a certain condition which should have excluded them

¹ According to the Complaint, Institutional Review Boards are private organizations to which the FDA outsources the task of supervising the safety of clinical trials and ensuring that FDA regulatory requirements pertaining to the clinical testing process are followed.

² An FDA Form 483 lists objectionable conditions observed by the FDA during a facility inspection. While the observations contained in a Form 483 report do not constitute a final agency determination regarding the facility’s compliance with applicable laws and regulations, corrective action by the inspected company is expected. Indeed, an establishment may face legal sanctions available to the FDA, such as seizure, injunction, civil monetary penalties and prosecution, if it does not voluntarily correct serious conditions. See Department of Health and Human Services, U.S. Food and Drug Administration Investigation Operations Manual 2007, at 214, 220, http://www.fda.gov/ora/inspect_ref/iom/pdf/chapter5.pdf (last visited July 11, 2007).

from a study were nonetheless allowed to participate.

The Complaint also describes grossly substandard conditions at the Miami testing facility, which accounted for over 60% of PDG's clinical trial facilities and over 30% of its profits. Though promoted by the company as "state of the art," the facility is described by the Complaint as a "converted Holiday Inn." Plaintiffs charge that the facility was expanded without the proper permits and in violation of building codes, rendering the structure unsafe. It was crammed with more than double the beds permitted by law and maintained in an unsanitary condition. The Miami Dade Building Department cited the facility for unsafe conditions over 80 times, over six years, dating back to October 1999. Ultimately, the Building Department ordered the Miami facility demolished, which cost PDG over \$26 million, or 20% of its revenues.

A number of other instances of misconduct left unaddressed by the directors are cited in the Complaint. PDG maintained inadequate internal controls with respect to related party transactions and failed to disclose the nepotism occurring at the company, described by the Complaint as "rampant." Executives without proper qualifications were hired, including defendant Krinsky as the company's chairman and director of medical trials even though she was not a licensed physician and defendant Seifer as the company's vice president of legal affairs even though he was not a lawyer. The Complaint also alleges that misrepresentations about the qualifications of executives were made in public filings and press releases, and that earnings for the first and second quarters of 2005 were overstated by \$609,000.

PDG's improper business practices and clinical testing transgressions came to light in an article published by Bloomberg News on November 2, 2005 entitled "Big Pharma's Shameful Secret." Several more articles exposing PDG's unethical and illegal activities were published

soon after. In or about late 2005, the United States Senate Finance Committee initiated an investigation into PDG's improper practices and unethical treatment of clinical trial participants.

PDG shareholders filed the first derivative action on January 24, 2006. On that date PDG's board consisted of six directors: defendants Levine, Holmes, Lucking, Golieb, Elias and non-defendant Jeffrey McMullen (collectively, the "Demand Directors"). Four were non-management outside directors. The two inside directors were Holmes and McMullen. Holmes served as President of Corporate Development until June 2006, and before that served as President of Early Clinical Development and Laboratories and Executive Vice President of Clinical Operations. McMullen became PDG's Chief Executive Officer in January 2006 and held that position at the time this litigation was initiated. The suit names various officers and directors of PDG as defendants. Insofar as it pertains to the instant motion to dismiss, the Complaint alleges that the Demand Directors are liable for failing to correct the widespread mismanagement of the company and egregious wrongdoing detailed above.

The various derivative actions were consolidated and transferred to this Court to proceed as a multidistrict litigation. In the Complaint, Plaintiffs admit that they did not make a demand on the board to bring the claims asserted in this lawsuit, claiming that demand would have been futile. Defendants move for dismissal on the grounds that Plaintiffs have failed to satisfy the heightened pleading standard for demand futility.

II. DISCUSSION

A. Standard of Review

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) may be granted only if, accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, a court finds that plaintiff has failed to set forth fair notice of what the claim is and the grounds upon which it rests. Bell Atlantic Corp. v. Twombly, 127 S.Ct. 1955, 1965 (2007) (citing Conley v. Gibson, 355 U.S. 41, 47 (1957)). A complaint will survive a motion under Rule 12(b)(6) if it states plausible grounds for plaintiff's entitlement to the relief sought. Id. at 1965-66 (abrogating Conley's standard that the "complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief"). In other words, it must contain sufficient factual allegations to raise a right to relief above the speculative level. Id. at 1965. The issue before the Court "is not whether plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence in support of the claims." Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1420 (3d Cir. 1997) (quoting Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)). In evaluating a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court may consider only the complaint, exhibits attached to the complaint, matters of public record, and undisputedly authentic documents if the complainant's claims are based upon those documents. See Pension Benefit Guar. Corp. v. White Consol. Indus., 998 F.2d 1192, 1196 (3d Cir. 1993).

A shareholder derivative action such as the case at bar implicates a heightened pleading standard. Federal Rule of Civil Procedure 23.1 provides, in pertinent part, that:

The complaint shall also allege with particularity the efforts, if any, made by the plaintiff to obtain the action the plaintiff desires from the directors or comparable authority, and if necessary, from the shareholders or members, and the reasons for the plaintiff's failure to obtain the action or for not making the effort.

Defendants argue that the Complaint must be dismissed for failure to plead with particularity the futility of making a demand on PDG's Board of Directors, a requirement that will be discussed in more detail below. Because PDG is a Delaware corporation, the substantive requirements of demand are governed in this case by Delaware law. Kamen v. Kemper Fin. Servs., Inc., 500 U.S. 90, 96-97 (1991). Thus, the issue is whether the Complaint contains sufficiently particularized facts under Delaware's substantive standards for determining that demand of the PDG board would have been futile.

B. Demand Futility

A derivative action is a procedural device that permits shareholders to assert a claim belonging to the corporation and on the corporation's behalf. Aronson v. Lewis, 473 A.2d 805, 811 (Del. 1984), overruled on other grounds by Brehm v. Eisner, 746 A.2d 244 (Del. 2000). Because such a suit impinges on the authority of a company's board of directors over matters of corporate governance, including whether to litigate a claim on behalf of the corporation, Delaware, like most jurisdictions, requires that shareholders make a demand on the board to take action. Rales v. Blasband, 634 A.2d 927, 932 (Del. 1993); Aronson, 473 A.2d at 811-12. It is well-settled that, to prosecute a derivative suit, shareholders must demonstrate that either a demand was made on the board and it was wrongfully refused or that demand should be excused because the directors are incapable of making an impartial decision regarding such litigation. Rales, 634 A.2d at 932.

This case implicates the demand futility exception to the requirement of pre-suit demand on the board. Because Plaintiffs do not challenge a specific action or decision of the board, but rather premise their breach of fiduciary duty and mismanagement claims on the board's failure to act, the Court must apply the demand futility test set forth by the Delaware Supreme Court in Rales v. Blasband. Rales, 634 A.2d at 933-34. Under Rales, demand is excused where the complaint raises a reasonable doubt that a majority of the directors are disinterested or independent. Id. at 930. The Rales court articulated the analysis as follows:

[A] court must determine whether or not the particularized factual allegations of a derivative stockholder complaint create a reasonable doubt that, as of the time the complaint is filed, the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand. If the derivative plaintiff satisfies this burden, then demand will be excused as futile.

Id. at 934.

Plaintiffs in this case have charged that a majority of the directors was both interested and not independent. Directorial interest exists where a director will receive a personal financial benefit from a transaction or where a corporate decision will have a materially detrimental impact on a director, but not on the corporation or the stockholders. Rales, 634 A.2d at 936. Where, as in this case, directors are sued for their failure to oversee subordinates, plaintiffs may raise a reasonable doubt as to the directors' disinterest by alleging particularized facts showing that directors face a substantial risk of personal liability for their conduct. In re Baxter Int'l, Inc. Shareholders Litig., 654 A.2d 1268, 1269 (Del. Ch. 1995). Independence refers to a director's decisionmaking "based on the corporate merits of the subject before the board rather than extraneous considerations or influences" such as the control or influence of an interested director.

Rales, 634 A.2d at 936-37; Aronson, 473 A.2d at 816.

C. Substantial Likelihood of Liability

Plaintiffs argue that demand should be excused, among other reasons, because all of the Demand Directors faced a substantial likelihood of personal liability for the misconduct charged in this lawsuit, preventing them from disinterestedly considering a demand by shareholders.

With respect to the futility of making a pre-suit demand, the Complaint alleges that the Demand Directors breached their fiduciary duties to PDG and its shareholders:

in that they failed to prevent and correct (i) PDG's improper recruiting practices in connection with its drug testing programs; (ii) conflicts of interests between PDG and Southern IRB, an institutional review board that was responsible for monitoring the safety of PDG's clinical operations in Miami; (iii) PDG's improper financial results for 1Q:05 and 2Q:05; (iv) PDG's false and misleading proxy statements; and (v) PDG's Relevant Period press releases that falsely portrayed the Company's financial results and business prospects. Thus, the PDG Board cannot exercise independent objective judgment in deciding whether to bring this action or whether to vigorously prosecute this action because its members are interestd personally in the outcome as it is their actions that have subjected PDG to millions of dollars in liability for possible violations of applicable securities laws.

(Complaint, ¶ 139(g).)

For reasons that will be discussed below, the Court concludes that Plaintiffs have pled with particularity that a majority of the Demand Directors had a disabling interest on the grounds that they faced personal liability for the alleged wrongdoing. This showing alone renders demand futile under Delaware law, and therefore, the Court need not address Plaintiffs' other arguments regarding director interest based on insider trading and the lack of independence of two Demand Directors.

Plaintiffs premise their theory of personal liability against the directors on their alleged failure to take any action to remedy the numerous problems plaguing PDG. This theory of liability was discussed by the Delaware Court of Chancery in In re Caremark International Inc. Derivative Litigation, and thus, in shortform, this claim is commonly referred to as a “Caremark” claim. In re Caremark Int’l Inc. Derivative Litig., 698 A.2d 959, 967 (Del. Ch. 1996). Unlike other theories of director liability, this claim does not involve allegations of conflict of interest, self-dealing or lack of loyalty by the directors. Id. Instead, the claim arises from loss to the corporation resulting from an unconsidered failure of the board to act. Id.

The elements of a Caremark claim are (1) that the directors knew or should have known that violations of law were occurring, (2) that the directors took no steps in a good faith effort to prevent or remedy that situation, and (3) that such failure proximately resulted in the losses complained of. Id. at 971. Directors, however, are generally insulated from liability by the business judgment rule for action, or in this case inaction, done in good faith. Aronson, 473 A.2d 805 (holding that the business judgment rule “is a presumption that in making a business decision the directors of a corporation acted on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the company”). Thus, the Caremark court explained that lack of good faith is a necessary condition to director liability. Caremark, 698 A.2d at 971. In the context of a Caremark claim, lack of good faith can be established by “a sustained or systematic failure of the board to exercise oversight.” Id.

D. Analysis

The Court finds that Plaintiffs have adequately pled a disabling personal interest of a majority of the directors who sat on the board on the date this suit was filed. The Complaint

contains particularized factual allegations showing that the Demand Directors faced a substantial risk of personal liability for their inattention to PDG's allegedly improper business and clinical testing practices. The wrongdoing detailed in the Complaint paints a picture of the kind of sustained and systematic failure of the board to exercise oversight over the company's operations that state a claim for breach of fiduciary duty involving bad faith. The primary business of PDG - drug trials involving human beings as test subjects - were routinely conducted in an egregiously unethical manner, compromising the data on products that could eventually reach the public and, more immediately, putting the safety of the participants at risk. The Complaint also describes a practice of preying on groups particularly vulnerable to PDG's financial inducements to participate in drug trials without protest regarding the conditions of treatment. As alleged, the violations are not isolated or rare occurrences. The Complaint avers that this was PDG's operating procedure, indeed, that it was the approach that enabled the company to secure and perform contracts for large drug trials.

Defendants argue that the Complaint fails to allege that the Demand Directors knew or should have known about the improper clinical practices or the building code violations of the Miami facility, a deficiency which would be fatal to a claim against the directors alleging breach of good faith and other fiduciary duties based on a failure to act rather than affirmative misfeasance. See, e.g., Stone v. Ritter, No. Civ. A. 1570-N, 2006 WL 302558, at *2 (Del. Ch. Jan. 26, 2006), aff'd sub. nom. Stone ex rel. AmSouth Bancorporation v. Ritter, 911 A.2d 362 (Del. 2006) (holding that to plead that directors faced a substantial likelihood of liability for failure to act, plaintiffs must allege with particularity facts "suggesting a conscious decision to take no action in response to red flags" of wrongdoing within the company); In re Baxter, 654

A.2d at 1270-71 (granting motion to dismiss because complaint did not plead with particularity that directors ignored obvious danger signs of employee wrongdoing). Defendants contend that there is no allegation that the majority of the board was involved in the day-to-day operations and thus, no basis on which to infer that the six-person board - which consisted of four non-management outside directors - knew about PDG's problems and consciously failed to take action to correct them.

The Complaint, however, alleges endemic mismanagement of the company, raising plenty of red flags concerning the improper and even possibly illegal practices in which the company was engaged. Plaintiffs allege with particularity the multiple test procedure violations detected by the FDA and the citations issued by the FDA against PDG. They detail abuses of the tests' human participants and deliberate falsification of test data, including a compensation structure for test subjects that discouraged the reporting of adverse effects. The Complaint also describes overcrowded and unsanitary conditions at PDG's principal Miami testing facility, located at the company's headquarters, with over 80 citations issued! Indeed, the Miami facility was ultimately condemned by the building department. IRBs with conflicts of interest were selected to monitor the trials.

Moreover, the alleged misconduct related to the core of PDG's business. PDG primarily engaged in the business of conducting clinical trials. The wrongful conduct alleged involved many critical aspects of the way in which PDG conducted clinical trials, including the treatment of people participating in the trials, overcrowded and unsanitary conditions at the testing facility located at the corporate headquarters, falsification and manipulation of the reporting of test results, and hiring conflicted IRBs to oversee the trials. This was not merely decentralized

activity by employees of a far-flung enterprise of the company, as was the case in Caremark. The PDG directors certainly should have known about the company's performance of its core business, and assuming the truth of Plaintiffs' allegations, about the particularly reprehensible manner in which it was done. Under these circumstances, the Court finds that the Complaint avers sufficient obvious signs of wrongdoing to support the allegation that the Demand Directors knew or should have known that they were not fulfilling their obligations by failing to take action in response to the company's widespread problems. In short, the Complaint contains "the kind of fact pleading that is critical to a Caremark claim," meaning that it shows the directors were conscious of the fact that they were not doing their jobs. Kanter v. Barella, — F.3d —, No. 05-5398, 2007 WL 1519894, at *6 (3d Cir. May 25, 2007) (quoting Guttman v. Huang, 823 A.2d 492 (Del. Ch. 2003)).

On the date the first derivative suit was filed, the PDG board consisted of six directors. Of these six, the Complaint identifies four of them - Levine, Holmes, Lucking, and Elias - as having been directors for the duration of the relevant time period. Golieb became a director in June 2005, and it is not clear from the Complaint when McMullen joined the board. Given the fact that at least four of the six Demand Directors sat on the board during a substantial part of, if not the entire time period during which these alleged abuses were occurring, the Court finds that a majority of the board faced a substantial likelihood of liability under the Caremark standard and thus could not disinterestedly consider a demand.³

³ In the case of a six-person board, demand would be futile if three of the directors were not disinterested or independent. An evenly divided board satisfies the requirement that a majority of the board be unable to consider a demand impartially. See Beam ex rel. Martha Stewart Living Omnimedia, Inc. v. Stewart, 845 A.2d 1040, 1046 n. 8 (Del. 2004) (citing Beneville v. York, 769 A.2d 80, 85-86 (Del. Ch. 2000)).

While the Court recognizes that the threshold for pleading a claim against directors based on a sustained failure to exercise oversight is high, see Caremark, 698 A.2d at 971, it finds that this case is one of those “rare” occurrences in which the directors have exposed themselves to liability by allegedly ignoring particularly flagrant and reprehensible wrongdoing, which unquestionably resulted in “a potentially life threatening situation” more immediately to the trials’ participants and in the longer-run to public consumers. In re Merck & Co., Inc. Securities, Derivative & ERISA Lit., — F.3d. — , No. 06-2911, 2007 WL 2049017, at *8 (3d Cir. July 18, 2007) (discussing that director passivity might expose him or her to liability only in face of truly egregious safety risks of which the director knows or should know); see also Seminaris v. Landa, 662 A.2d 1350, 1354 (Del. Ch. 1995) (observing that Delaware Supreme Court envisioned the possibility of the rare case in which director conduct was so egregious as to create a substantial likelihood of liability) (citing Aronson, 473 A.2d at 815); cf. In re Tower Air, 416 F.3d 229, 239 (3d Cir. 2005) (reversing district court’s dismissal of breach of fiduciary duty claim in direct action by bankruptcy trustee against directors, reasoning that directors were exposed to liability for inaction in face of known misconduct implicating safety of public because only explanation for such passivity is bad faith). Moreover, this conduct appears to have been so endemic, with repeated documented violations filed by both the FDA and local authorities, that it is inconceivable that a board of directors properly performing its functions would not have known about the wrongdoing.

The inquiry before the Court on this motion to dismiss bears repeating. The Court is not ruling on the ultimate merits of the alleged claims, nor is it even venturing to guess whether Plaintiffs can prevail on the claims. The question before the Court is whether the alleged facts

raise a reason to doubt that the directors are disinterested. In re Walt Disney Co. Derivative Litig., 825 A.2d 275, 289 (Del. Ch. 2003). The Court finds that this standard of pleading demand futility has been met. In short, the Complaint states a cognizable claim, and Plaintiffs are entitled to offer evidence in support of their claim.

The exculpatory provision of PDG's certificate of incorporation fails to carry Defendants' motion.⁴ Defendants argue that the exculpatory provision frustrates Plaintiffs' effort to demonstrate a disabling interest of the majority of the Demand Directors. The provision, in relevant part, states as follows:

No director of this Company shall be personally liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director. Nothing in this Section 9 shall serve to eliminate or limit the liability of a director (a) for any breach of the director's duty of loyalty to the Company or its stockholders, (b) for acts or omissions not in good faith or which involves [sic] intentional misconduct or a knowing violation of law . . . If the Delaware General Corporation Law is amended after approval by the stockholders to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Company shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

Under current Delaware law, a corporation may not exempt its directors from liability for violations of the duties of loyalty and good faith, consistent with the exculpatory provision contained in PDG's certificate of incorporation. 8 Del. C. § 102(b)(7).

“When the certificate of incorporation exempts directors from liability, the risk of liability does not disable them from considering a demand fairly unless particularized pleading permits

⁴ The Court appropriately takes judicial notice of the certificate in deciding the instant motion to dismiss. In re Baxter, 654 A.2d at 1270.

the court to conclude that there is a substantial likelihood that their conduct falls outside the exemption.” In re Baxter, 654 A.2d at 1270. In this case Plaintiffs allege, among other things, that Defendants, including the Demand Directors, breached their fiduciary duty of good faith by failing to take corrective action in response to the obvious signs of wrongdoing. Plaintiffs’ claims, as pled, fall outside the exculpatory provision. For the reasons discussed above, the Court finds that Plaintiffs have sufficiently pled a breach of fiduciary duty by the Demand Directors involving bad faith. Thus, they are not shielded from liability by either the exculpatory provision or Delaware statutory law. Emerald Partners v. Berlin, 787 A.2d 85, 94 (Del. 2001).

In sum, this Court finds that Plaintiffs have adequately pled that the board could not have impartially considered a demand at the time this litigation was filed on the grounds that a majority of the Demand Directors faced a substantial likelihood of personal liability for the misconduct complained of by the Plaintiffs. Though the derivative suit is an extraordinary procedural device, the Court finds that the circumstances of this case warrant its use, in spite of the shareholders’ failure to demand that the company directors bring the suit in the corporation’s name. The alleged wrongs to PDG involve practices that risked the well-being of people participating in clinical trials run by the company as well as the well-being of the public by misleading pharmaceutical companies about the safety and/or efficacy of the tested products. For the reasons discussed above, the Court finds that the Complaint’s allegations describe mismanagement that was severe and endemic enough to give rise to a plausible claim of director liability based on the failure to remedy the problems. Having raised reasonable doubt as to the

Demand Directors' disinterestedness, Plaintiffs have demonstrated that it would have been futile to make a pre-suit demand on the board. Thus, the Complaint survives Defendants' motion to dismiss.

III. CONCLUSION

For the foregoing reasons, the Court denies Defendants' motions to dismiss. An appropriate form of Order will be filed.

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

Dated: July 25, 2007